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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,603	06/08/2005	Tatsuhiko Kodama	14875-0137US1	5647

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EXAMINER	
NOBLE, MARCIA STEPHENS	

ART UNIT	PAPER NUMBER
1632	

NOTIFICATION DATE	DELIVERY MODE
08/19/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	10/516,603	KODAMA ET AL.	
	Examiner	Art Unit	
	MARCIA S. NOBLE	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22 and 23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 December 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/8/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 22 and 23 are pending. Claims 19 and 21 are canceled and claims 22 and 23 are newly added by the response, filed 5/15/2009. Claims 22 and 23 are under consideration.

Withdrawn Rejection and Allowable Subject Matter

The rejection of claim 21, provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11, 12, and 14 of copending Application No. 10/594,690, in the amendment filed 9/29/2008, as set forth in the Office Action, mailed 1/27/2009 (pp. 2-4), is withdrawn.

Claim 19 was deemed allowable in the Office Action, mailed 1/27/2009 (p. 4). However, claim 19 is now canceled and the deemed allowable subject matter statement is therefore moot.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22 and 23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

A method of producing an antibody against PepT1, wherein the method comprises the steps of: (a) immunizing a transgenic mouse with an immunogen comprising a budding baculovirus, wherein the baculovirus where expresses a PepT1 or a fragment thereof on the surface of the baculovirus, wherein the genome of the transgenic mouse comprises a gene encoding a baculovirus membrane protein gp64, and wherein the transgenic mouse expresses the baculovirus membrane protein gp64 and has immunotolerance to gp64; and (b) recovering an antibody recognizing PepT1 from the immunized transgenic mouse; and

A method of producing an antibody against antigen, wherein the method comprises the steps of: (a) immunizing a transgenic mouse with an immunogen comprising a budding baculovirus, wherein the baculovirus where expresses an antigen or an epitope thereof on the surface of the baculovirus, wherein the genome of the transgenic mouse comprises a gene encoding a baculovirus membrane protein gp64, and wherein the transgenic mouse expresses the baculovirus membrane protein gp64 and has immunotolerance to gp64; and (b) recovering an antibody recognizing the antigen or epitope thereof from the immunized transgenic mouse, does not reasonably provide enablement for 1) any virus other than a baculovirus; 2) a fraction of a virus; or 3) a baculovirus that does not express PepT1 or the antigen on the surface of the baculovirus. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

While determining whether a specification is enabling, one considers whether the claimed invention provides sufficient guidance to make or use the claimed invention, if not, whether an artisan would require undue experimentation to make and use the claimed invention and whether working examples have been provided. When determining whether a specification meets the enablement requirements, some of the factors that need to be analyzed are: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and whether the quantity of any necessary experimentation to make or use the invention based on the content of the disclosure is "undue".

1) The breadth of the claims encompasses the use of any budding virus to immunize a transgenic mouse expressing a baculovirus gp64 membrane protein. The specification teaches that the production of antibodies to an antigen of interest using baculovirus expression systems expressing the antigen of interest is hindered by the presence of the baculovirus gp64 membrane protein. Baculovirus have an abundance of gp64 and gp64 in highly immunogen. Thus, the gp64 interferes with the specific production and isolation of antibodies to antigens of interest (p. 2, lines 2-25). To overcome this hindrance to antibody production, the inventors produced transgenic mice that express baculovirus gp64 membrane protein and thus are immunotolerant to the gp64 membrane protein. As a consequence, these mice can be immunized with baculovirus systems expressing antigens of interest and will not have the artifact of producing gp64 antibodies (p. 3, lines 1-7 of the specification). However, the claims are

drawn to the immunization of the gp64 transgenic mouse with any virus. The specification fails to teach any other viral expression systems that will work with the present invention. Further, the specification teaches the mechanism by which the instant method function is immunotolerance to the gp64 protein specific to baculovirus. Thus, another virus would not function in the instant invention because the system is tailored to the baculoviral expression systems. Therefore, the specification only enables the use of a budding baculovirus in the instant invention and does not enable the breadth of any virus.

2) and 3) The claims recite the use of a fraction of a budding baculovirus to immunize the gp64 transgenic mouse. However, the specification fails to enable those of skill in the art at the time of filing to immunize the transgenic mouse with an immunogen comprising a fraction of the baculovirus as broadly claimed. The specification fails to teach how to introduce the target antigen in context of a fraction of a baculovirus. The specification fails to teach how to immunize without the target antigen being expressed by the baculovirus. The specification fails to teach how to introduce the target antigen expressed inside the baculoviral particle and not with the envelope proteins on the surface of the particle. If the target antigen is not expressed in context of baculovirus, then using the gp64 transgenic mouse is moot because the method can be performed with a wild-type mouse. If the target antigen is expressed inside the baculoviral particle but not displayed on the surface, the antigen would not induce an antibody response because the humoral immune system (for antibody production) would not have access to a target antigen. The specification fails to teach

how to immunize with a baculovirus expressing a non-membrane protein. Thus, it would have required those of skill undue experimentation to determine how to obtain antibodies against the target antigen.

Therefore at the time of filing the skilled artisan would need to perform an undue amount of experimentation without a predictable degree of success to implement the invention as claimed.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCIA S. NOBLE whose telephone number is (571)272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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